UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE Y-mAbs THERAPEUTICS, INC. SECURITIES LITIGATION	Civil Action No.: 1:23-cv-00431-JMF **CLASS ACTION**
THIS DOCUMENT RELATES TO: ALL ACTIONS	**AMENDED CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

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NATURE OF THE ACTION

1. This is a securities fraud class action brought by Lead Plaintiff Omar Miramontes ("Plaintiff") individually and on behalf of all other persons similarly situated, by his undersigned counsel. The action charges that the defendants named herein violated 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") (15 U.S.C. §§ 78j(b), 78t(a) and 78t(b)), and Rule 10b-5 promulgated thereunder by the U.S. Securities and Exchange Commission (the "SEC") (17 C.F.R. § 240.10b-5) (the "Action").

2. The Action is brought on behalf of all investors who purchased or otherwise acquired the common stock of Y-mAbs Therapeutics, Inc. ("Y-mAbs" or the "Company"), during the period October 6, 2020 through October 28, 2022, inclusive (the "Class Period").

3. Plaintiff's allegations are based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through their attorneys, which included, among other things, a review of the defendants' public documents, conference calls and announcements made by defendants, SEC filings, wire and press releases published by and regarding Y-mAbs, analysts' reports and advisories about the Company, and information readily obtainable on the Internet, including the website of the U.S. Food and Drug Administration ("FDA"), including FDA Briefing Document issued on October 26, 2022 ("Briefing Document").[1] Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

[1] A copy of FDA Briefing Document is annexed hereto as Exhibit A.

PRELIMINARY STATEMENT

4. Y-mAbs is a clinical-stage biopharmaceutical company focused on developing antibody therapeutics and medicines for the treatment of cancer patients.

5. During the Class Period, the Company's "lead product candidate" was ^{131}I-Omburtamab,[2] which was designed to treat pediatric patients with neuroblastoma that relapsed in the central nervous system ("CNS") or leptomeninges ("LM").

6. Y-mAbs requested FDA approval to distribute omburtamab through a Biologics License Application ("BLA") seeking to demonstrate efficacy of omburtamab by comparing the overall survival ("OS") results in the single-arm "Study 03-133" with an external control constructed from data from the Central German Childhood Cancer Registry ("CGCCR"), which included clinical data from patients with neuroblastoma included in German clinical trials from 1990 to 2015.

7. On October 5, 2020, after the close of trading, Y-mAbs issued a press release informing investors that it had received a Refusal To File ("RTF") letter from FDA regarding its BLA for omburtamab. In the press release and during a conference call on October 6, 2020, Defendants assured investors that the RTF was issued merely because FDA wanted additional information rather than because of any substantive deficiencies with the BLA. Defendants told investors that the request for the additional information was a "surprise" and constituted only a "minor setback," stating that "it's not a problem," the Company "is confident that it can address all points raised by the FDA" and easily "rectify" the situation by the end of 2020. Defendants assured investors that approval was a sure thing, proclaiming there was "no concern that the

[2] ^{131}I-Omburtamab is referred to herein (except where quoted) as "omburtamab."

FDA will think, 'Oh, that is not sufficient response'" because FDA "want to work with us on getting this successfully refiled and approved as quickly as possible."

8. In truth, Defendants knew but failed to disclose that FDA had determined that the "application did not contain substantial evidence consisting of adequate and well-controlled investigations that 131I-omburtamab is safe and effective." Defendants also knew that Y-mAbs would have difficulty addressing FDA's concerns, if possible at all, because FDA had met with and corresponded with Y-mAbs throughout 2017 to 2020, and had repeatedly advised Y-mAbs of its concerns that (a) the patient population in Study 03-133 was not comparable to the population in CGCCR, (b) even if the two populations were "fit-for-purpose," direct evidence of the anti-tumor effect of omburtamab as determined by a blinded independent radiology committee would be needed to demonstrate efficacy, and (c) such interpretation of such evidence would be "difficult" because Y-mAbs was relying on a "single-arm trial."

9. As Y-mAbs and FDA discussed the possible resubmission of the BLA throughout the Class Period, FDA again repeatedly warned Y-mAbs that "the CGCCR external control was not fit-for-purpose due to lack of granular patient-level data" and was not an adequate comparator for the overall survival data from patients in Study 03-133 because, among other things, patients in Study 03-133 received more intensive cancer treatments (both in number and types of treatment) than the patients in the CGCCR, which biased the results in favor of omburtamab because these other treatments (not omburtamab) could explain the positive results observed in Study 03-133. For example, 91% of patients in Study 03-133 received craniospinal irradiation – a leading treatment for the disease – whereas ***zero patients in CGCCR received that treatment***.

10. FDA also told Y-mAbs that even if the CGCCR control was adequate, the Company would still need "***compelling response data***" demonstrating the anti-tumor effect of

omburtamab. While Y-mAbs had interim data from its "Study 101," which sought to establish direct evidence of anti-tumor effect of omburtamab through assessment of MRI, ***no patient in Study 101 demonstrated an unequivocal treatment response that could be definitively attributed to omburtamab***.

11. FDA also told Y-mAbs that if they could not reach agreement on the data to be included in the resubmitted BLA and "if ultimately FDA cannot determine if the patient populations are similar enough…an alternative clinical development program will need to be discussed."

12. Despite these dire warnings, Defendants continued to tout the results of Study 03-133 and reassure investors that "we have resolved all the issues that [FDA] have requested," Y-mAbs was "aligned with the FDA on the next steps," and they had a "clear path forward towards the resubmission," which was "progressing well" and "as planned." Defendants even proclaimed that "the FDA seems to be very happy about [the granularity and details of data obtained]."

13. Moreover, after having repeatedly assured investors that Y-mAbs would not resubmit the BLA until they "reach a final agreement with [FDA] on the remaining details" and "get a green light," on February 25, 2022, Defendants falsely stated that FDA had "confirmed our path towards a BLA resubmission in March" and on April 1, 2022, announced that it had successfully completed the resubmission of its BLA. Defendants concealed from investors that (i) that FDA had expressly told Y-mAbs at a recent meeting "that there was insufficient information to provide agreement on the efficacy package to support the BLA" and had determined that certain aspects of Y-mAbs' proposed analysis ""appeared arbitrary," and (ii) the Company had elected to resubmit the BLA despite lacking agreement with FDA on the content of the application.

14. Investors finally learned the truth on October 26, 2022, when FDA publicly released its Briefing Document for the Oncologic Drugs Advisory Committee Meeting scheduled for October 28, 2022. FDA concluded that the "difference in survival cannot be reliably attributed to omburtamab," identifying three key issues with the application submitted by Y-mAbs: "(1) The external control population is not fit-for-purpose as a comparator due to substantive differences between the study and control populations that limit the ability to attribute survival differences to the effect of Omburtamab; (2) recognizing the level of evidence provided and need for regulatory flexibility, FDA performed additional analyses to examine bias and results reinforce that differences in survival cannot be reliably attributed to Omburtamab; (3) the application does not include reliable response rate data to provide supportive evidence of the treatment effect of Omburtamab." Indeed, FDA revealed: "***Overall, no patient in Study 101 demonstrated an unequivocal treatment response that could be definitively attributed to omburtamab***"

15. The Briefing Document highlighted the fact that FDA had repeatedly warned Y-mAbs over the course of years that the CGCCR external control data was not "fit-for-purpose" as a direct comparator because of significant differences in the patient population and treatments. Driving home the point that Y-mAbs failed to heed FDA's repeated warnings, the Briefing Document included two tables summarizing the numerous communications with Y-mAbs in which FDA expressed its concerns, utilizing **bolded** text to emphasize that Y-mAbs knew that the application would fail. And during the subsequent Advisory Committee meeting, FDA stated:

> ***Early on, we cautioned*** on the complexity of the proposed external control design ***and consistently highlighted*** that the ability to interpret the data would largely depend on the comparability of the populations and the ability to isolate the treatment effect of omburtamab from other therapies…***As we advised the applicant in prior meetings***, the receipt of so much intensive treatment prior to

> administration of omburtamab would be an important prognostic variable when matching to a control and ***would likely make it difficult to determine if any effects on survival are due to omburtamab and not to those treatments***. (emphasis added).

16. Further emphasizing the fact that Y-mAbs knew that the submission was doomed, the Briefing Document emphasized that Y-mAbs never received approval from FDA to resubmit the BLA, stating "[o]n March 31, 2022, Y-mAbs elected to resubmit the BLA on March 31, 2022 prior to reaching agreement with the FDA on the content of the application."

17. On Friday, October 28, 2022, after the close of trading, Y-mAbs informed investors that FDA Advisory Committee had voted ***unanimously*** 16 to 0 that Y-mAbs had not provided sufficient evidence to conclude that omburtamab improved overall survival. The grounds for denial were precisely the same grounds that Y-mAbs was apprised of by FDA during its numerous communications prior to submitting the BLA.

18. The disclosure of the truth caused Y-mAbs common shares to plummet $11.56 a share from the closing price of $15.17 a share on October 25, 2022 to $3.61 a share on October 31, 2022.

JURISDICTION AND VENUE

19. This action arises under Sections 10(b) (15 U.S.C. § 78j(b)) and 20(a) (15 U.S.C. § 78t(a)) of the Exchange Act, 15 U.S.C. § 78a et seq., and Rule 10b-5 (17 C.F.R. § 240.10b-5) promulgated thereunder by the SEC.

20. Jurisdiction is conferred upon this Court by Section 27 of the Exchange Act (15 U.S.C. § 78aa), which vests exclusive jurisdiction for actions alleging violations of the Exchange Act in federal courts, and federal question jurisdiction (28 U.S.C. § 1331).

21. Venue is proper in this District because Y-mAbs maintained offices in this District during the Class Period and many of the acts and transactions constituting the violations of law herein complained of occurred within this District, including the preparation and

dissemination of materially false and misleading financial statements and corporate documents. Additionally, the Company's common stock trades on the NASDAQ Stock Exchange Global Market (NASDAQ"), located within this District.

22. In connection with the acts alleged herein, the Defendants directly or indirectly used the means and instrumentalities of interstate commerce, including the United States mails and facilities of a national securities exchange.

PARTIES

23. Plaintiff, as set forth in the previously-filed certification (ECF No. 28-3), incorporated by reference herein, purchased Y-mAbs common stock at artificially inflated prices during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

24. Defendant Y-mAbs is a Delaware corporation, with its principal executive offices located at 230 Park Avenue, Suite 3350, New York, New York 10169. Y-mAbs stock trades on the NASDAQ under the symbol "YMAB".

25. Y-mAbs is a clinical-stage biopharmaceutical company focused on developing antibody therapeutics and medicines for the treatment of cancer patients. Y-mAbs's development processes are subject to FDA oversight and approval. During the Class Period, Y-mAbs had approximately 130 employees.

26. Defendant Thomas Gad ("Gad") is the Founder, and current Board Member, President, interim Chief Executive Officer, and Head of Business Development and Strategy, of Y-mAbs, having founded Y-mAbs in April 2015. Gad had actual knowledge and supervision over Y-mAbs's communications with FDA and the true (undisclosed) facts concerning FDA approval process. For example, during the October 28, 2022 FDA Oncologic Drugs Advisory

Committee Meeting discussing the BLA for omburtamab, Gad attended and provided introductory remarks on behalf of Y-mAbs's BLA.

27. Defendant Claus Juan Moller San Pedro ("Moller") was Y-mAbs's Chief Executive Officer from June 2015 until April 2022 and acted as the Interim Chief Commercial Officer from December 2021 until January 2022. Moller, as Y-mAbs CEO, had actual knowledge and supervision over Y-mAb's communications with FDA.

28. Defendant Vignesh Rajah ("Rajah") has been Y-mAbs Senior Vice President, Chief Medical Officer, and Head of Late-Stage Development since June 2020. Rajah is identified on Y-mAbs website as a member of the Company's "Leadership" of "Corporate Governance." Rajah had actual knowledge and supervision over Y-mAbs's communications with FDA. For example, during the October 28, 2022 FDA Oncologic Drugs Advisory Committee Meeting discussing the BLA for omburtamab, Rajah gave Y-mAbs's presentation on the efficacy and safety of omburtamab and was responsible for answering questions from the Advisory Committee.

29. Defendants Gad, Moller, and Rajah are sometimes referred to herein as the "Individual Defendants."

30. The Individual Defendants made, disseminated, or oversaw the publication of, the public statements alleged to be materially false and misleading herein.

SUBSTANTIVE ALLEGATIONS

I. Y-MABS AND OMBURTAMAB

31. Y-mAbs is a biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products for the treatment of cancer.

32. During the Class Period, Y-mAbs stated that the Company's "lead product candidate" was omburtamab. Omburtamab is a murine monoclonal antibody that targets B7-H3,

an immune checkpoint molecule that is widely expressed in tumor cells of several cancer types. "^{131}I-Omburtamab" is omburtamab radiolabeled with Iodine-131.

33. Omburtamab was designed to treat pediatric patients with neuroblastoma that relapsed in the central nervous system or leptomeninges. Leptomeningeal metastases occurs when cancer cells have spread to thin layers of tissue that cover the brain and spinal cord.

34. Neuroblastoma is a childhood cancer that originates in the sympathetic nervous system, typically occurring in or near the adrenal glands. It accounts for 7-10% of childhood cancers, with more than 650 cases diagnosed per year in the US. Approximately 3% of patients who experience metastatic relapse have metastases to the CNS or LM.

35. There are currently no FDA-approved therapies for neuroblastoma with CNS/LM relapse and standard of care is not well defined. A typical treatment approach in the US includes radiation therapy, specifically craniospinal irradiation. Chemotherapy has also been suggested as a treatment.

36. Median survival with CNS/LM relapse has historically been reported to be less than one year; however, survival has improved over time and long-term remission has been reported in patients who received craniospinal irradiation and chemotherapy. Specifically, survival has improved over the past 2 decades.

37. Development of omburtamab was initiated by Memorial Sloan Kettering Cancer Center ("MSKCC") with "Study 03-133," which was a single-center investigator-initiated single-arm trial. As a single-arm trial, Study 03-133 had no control group. The trial was conducted at MSKCC and included pediatric patients with CNS/LM relapsed neuroblastoma.

38. The trial was initiated in 2004 with enrollment closing in 2018. The trial was not originally intended to provide evidence of efficacy, with an initial planned enrollment of only 30 patients in the original protocol; however, additional patients were enrolled as part of a dose-

expansion component that was subsequently added to the protocol. The efficacy population consisted of a subset of 94 patients with CNS/LM relapsed neuroblastoma who received omburtamab at a dose based on age. The primary endpoint in Study 03-133 was overall survival at 3 years. Overall survival was calculated from the date of first diagnosis of CNS/LM relapse until death or the latest date the patient was confirmed to be alive.

39. After CNS/LM relapse and prior to receiving omburtamab, all patients received at least one type of CNS-directed therapy, including surgery (83%), chemotherapy (98%), and radiotherapy (93%). The majority (76%) of patients received all three treatment modalities.

40. Study 03-133 did not analyze tumor responses.

41. The 3-year OS rate after CNS/LM relapse in the efficacy population of 94 patients was 54%.

42. Y-mAbs sought to demonstrate efficacy of omburtamab by comparing the overall survival results in the single-arm Study 03-133 with an external control constructed from data from the CGCCR, which includes clinical data from patients with Stage 4 neuroblastoma included in German national neuroblastoma clinical trials from 1990 to 2015.

II. FDA REGULATORY BACKGROUND

43. 21 CFR 314.126 contains the elements required to be satisfied in order to receive FDA approval for omburtamab. A drug or biologic product must demonstrate substantial evidence of effectiveness through adequate and well-controlled studies.

44. "Substantial evidence of effectiveness" must be established by two or more adequate and well-controlled trials or by a single adequate and well-controlled trial with supportive evidence. *See* FDA draft guidance for industry, *Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products*, 2019. The quality of clinical evidence to establish effectiveness and the resulting level of certainty about the demonstration

of substantial evidence is impacted by the selection of trial design and endpoints, as well as statistical considerations. The "substantial evidence" of effectiveness standard in the statute refers to both the quality and quantity of evidence. In 1962, Congress defined substantial evidence as "evidence consisting of adequate and well-controlled investigations…on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have…" FD&C Act section 505(d); 21 U.S.C. § 355(d).

45. To establish a drug's effectiveness, it is essential to distinguish the effect of the drug "from other influences, such as spontaneous change in the course of the disease, placebo effect, ***or biased observation***." 21 CFR 314.126 (emphasis added).

46. In oncology, overall survival is typically considered the gold standard efficacy endpoint to support traditional approval since prolongation of survival is a direct clinical benefit and also reflects drug safety. For regulatory purposes, randomized trials are needed with rare exception to assess the effect of a drug on overall survival because randomization controls for both known and unknown prognostic factors.

47. In a randomized trial, patients are assigned to different treatment groups. For example, some patients may be assigned to the investigational therapy and the rest of the patients to another drug or standard of care for the same disease. This allows researchers to control for other factors that could impact the results, ensuring that whatever results are obtained there is high confidence that they are the result of the drug being studied and not some other factor.

48. By contrast, in a single-arm trial, all patients receive the investigational drug and the researchers aim to evaluate its safety and effectiveness by comparing it to data external to the study. As discussed in the 2019 FDA draft guidance for industry, *Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products*, externally controlled trials

differ in several important ways from randomized trials. Most notably, randomization is not a feature of external control designs. As a result, there may be differences in baseline patient characteristics or concomitant treatments in the trial population compared to the external control population that lead to differences in outcomes that are unrelated to the investigational treatment. In addition to the lack of ability to eliminate systematic differences between nonconcurrent groups, the lack of blinding can introduce bias into treatment decisions and assessment of outcomes in the investigational arm. *See* FDA guidance for industry, *Rare Diseases: Common Issues in Drug Development* (2019). This significantly increases the risk that any observed efficacy could be the result of other factors, such as additional treatments, standard of care, or the varying baseline condition of the patients.

49. As discussed in FDA guidance for industry *Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics* (December 2018), overall survival should generally be evaluated in randomized trials because data from externally controlled trials may not be reliable or interpretable. Apparent differences in outcome between external controls and current treatment groups can arise from factors other than the drug under investigation, such as differences in patient or disease characteristics, supportive care, concomitant treatments, or other factors. Randomized studies minimize the effect of both known and unknown differences between populations by providing a direct outcome comparison.

50. The inability to eliminate systematic differences between nonconcurrent treatment groups is a major limitation of externally controlled designs. This limitation generally restricts use of external control designs to assessment of serious disease when a randomized trial is not feasible or ethical, and when certain conditions are present.

51. In specific circumstances, such as when randomized trials are not feasible or ethical, an adequate and well-controlled single-arm trial may rely on an external control;

however regulations stipulate that the comparison of the results of treatment occur in "comparable patients or populations." 21 CFR 314.126. In such circumstances, efficacy in oncology single-arm trials has relied on objective tumor response which removes the uncertainty around attribution of the effect to the drug under study rather than other confounding influences.

52. As described in FDA draft guidance for industry, *Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products*, (2019) and *Rare Diseases: Common Issues in Drug Development* (2019), the following characteristics can strengthen the level of support for effectiveness provided by an externally controlled trial:

- the natural history of a disease is well defined (*i.e.*, has a highly predictable disease course that can be objectively measured and verified),
- the external control population is very similar to that of the treatment group,
- concomitant treatments that affect the primary endpoint are not substantially different between the external control population and the trial population, and
- the results provide compelling evidence of a change in the established progression of disease (such as partial or complete response in a disease where spontaneous regression is not observed).

53. FDA has recognized that it is appropriate to exert regulatory flexibility in applying the statutory standards of safety and effectiveness in the evaluation of new therapies intended to treat persons with life-threatening illnesses, particularly when there is no satisfactory alternative therapy. *See* 21 CFR 312, subpart E (21 CFR 312.8). Nevertheless, the requirement for substantial evidence of effectiveness generated by an adequate and well controlled trial with supportive evidence or two or more adequate and well-controlled trials applies irrespective of the degree of unmet medical need.

III. THE EXTERNAL CONTROL FROM CGCCR COULD NOT SUPPORT EFFICACY OF OMBURTAMAB BECAUSE IT WAS NOT "FIT FOR PURPOSE" AS A COMPARATOR

54. Y-mAbs sought FDA approval to distribute omburtamab through a BLA. As with other types of FDA approval, Y-mAbs was required to demonstrate the efficacy and safety of omburtamab.

55. Y-mAbs sought to demonstrate the efficacy of omburtamab by comparing the overall survival results in the single-arm Study 03-133 with an external control constructed from data from the CGCCR, which includes clinical data from patients with Stage 4 neuroblastoma included in German national neuroblastoma clinical trials from 1990 to 2015.

56. The external control population from CGCCR was not "fit-for-purpose" as a comparator, preventing attribution of the survival differences to the effect of omburtamab.

57. ***First***, although patients with CNS/LM relapsed neuroblastoma have a generally poor prognosis, survival has improved over time as additional treatments have been applied. Study 03-133 included patients that relapsed between 2005 and 2018, whereas CGCCR included patients that relapsed between 1991 and 2020. Because the patients in the external control were not treated contemporaneous with those in Study 03-133 and available data indicate that OS in patients with CNS/LM neuroblastoma has improved over time, the results were biased in favor of Study 03-133.

58. For example, patients in the CGCCR external control treated between 1990 and 2005 (prior to the start of Study 03-133) had a median OS of ***9.6 months***. Patients in the external control treated between 2005 and 2020 (which overlapped with Study 03-133) had a median OS of ***15.7 months***.

59. ***Second***, there were significant population differences resulting in Study 03-133 having better "baseline clinical status." In order to qualify for enrollment in Study 03-133 and

receive omburtamab, patients had to be well enough to travel to MSKCC and sufficiently recovered from intensive multimodality treatment; this differed from the selection criteria for the external control, which had no such requirement. Because patients enrolled in Study 03-133 had to have sufficiently recovered from prior CNS-directed treatment to travel to the MSKCC site and receive omburtamab, the higher OS rate from Study 03-133 could be the result of the study not including the patients least likely to survive, which were included in the CGCCR dataset.

60. ***Third***, in measuring OS for Study 03-133 and the external control, Y-mAbs used as a start date the last post-CNS relapse treatment. However, because every patient included in Study 03-133, by definition, must have survived for the months between their last treatment and traveling to MSKCC to receive omburtamab, using this start date biased any analysis of survival time in favor of the Study 03-133 population because patients were not required to have survived any period of time following post-CNS relapse treatment to be included in the external control population. Notably, the median time between patients' last treatment and receiving omburtamab was 3.1 months. During that time period, 30% of patients in the external control died. Therefore, the higher OS rate from Study 03-133 could be the result of the study not including the potential population of patients that died during this time, which were included in the CGCCR dataset.

61. ***Fourth***, the approach to treatment of CNS relapse treatment differed between the Study 03-133 and the CGCCR external control populations, with patients in Study 03-133 generally receiving more intensive treatment. Common treatments for CNS/LM relapse are (i) radiation therapy, (ii) craniospinal irradiation, and (iii) chemotherapy. The number of post-relapse therapy received by patients clearly impacts the patients OS. Patients in Study 03-133 received multimodality treatment for CNS/LM relapse prior to omburtamab that was generally

more intensive, both in terms of number and types of treatment, than treatment in the external control population. This biased the results in favor of omburtamab because there was a clear trend toward improved survival with higher treatment intensity in the external control population. For example, for the 79 patients who received at least one treatment modality for CNS/LM relapse in the CGCCR external control, the 3-year OS rate from the time of CNS relapse ***was 15%***. In the subset of patients who received radiation, surgery, and chemotherapy, the 3-year OS rate ***was 38%***.

62. For patients who received at least one post-relapse therapy (surgery, radiation, or chemotherapy), the median OS in the external control was ***9.9 months***. For patients who received post-relapse radiation therapy and at least one other treatment modality (surgery or chemotherapy), the median OS in the external control was ***16.0 months***. For patients who received post-relapse radiation therapy, surgery ***and*** chemotherapy), the median OS in the external control was ***29.8 months***. This demonstrated a clear trend for improved survival in patients in the external control population who received CNS-directed therapy that was more comparable to treatment received by Study 03-133 patients; highlighting the magnitude of uncertainty associated with attribution of survival differences to omburtamab based on OS comparisons between the Study 03-133 and external control populations.

63. This trend clearly biased the results of Study 03-133 over the CGCCR external control population. ***While 76% of patients in Study 03-133 received all three treatments, only 27% of patients in CGCCR received all three treatments***. Indeed, 91% of patients in Study 03-133 received craniospinal irradiation whereas ***zero patients in CGCCR received that treatment***.

64. ***Fifth***, the gap in treatment intensity was likely even wider than what is reflected by the above figures because post-omburtamab treatment was not systemically captured in Study 03-133. However, based on typical US treatment practices, it is likely that many patients

in Study 03-133 received additional therapy following omburtamab which could contribute to longer survival.

65. ***Sixth***, there are other potential sources of bias due to population selection and differences in treatment patterns between countries and over time. Additionally, there are potential differences in clinical care between the United States and Germany that could impact the results.

IV. Y-MABS DID NOT SUBMIT RELIABLE TUMOR RESPONSE RATE DATA AS NO PATIENT IN STUDY 101 DEMONSTRATED A RESPONSE THAT COULD BE UNEQUIVOCALLY ATTRIBUTED TO OMBURTAMAB

66. As discussed above, efficacy in oncology single-arm trials has relied on objective tumor response which removes the uncertainty around attribution of the effect to the drug under study rather than other confounding influences.

67. To this end, Y-mAbs sought to demonstrate efficacy of omburtamab by also including interim data from "Study 101," which was another single-arm trial conducted by Y-mAbs. In addition to a primary endpoint of 3-year OS rate (like Study 03-133), it also sought to establish direct evidence of an anti-tumor effect of omburtamab through a secondary endpoint of overall response rate ("ORR") (which was not collected in Study 03-133.

68. In Study 101, tumors were assessed by MRI at 5-, 10-, and 26-weeks after the first dose of omburtamab and evaluated by a blinded independent central review ("BICR"). Response Assessment in Neuro-Oncology ("RANO") group criteria for brain metastasis were used to assess parenchymal disease; these criteria require confirmation of response by a second imaging assessment obtained at least 4 weeks following the first image documenting a response. European Association of Neuro-Oncology-European Society for Medical Oncology ("EANO-ESMO") guidelines were used to assess response for LM metastases.

69. When Y-mAbs submitted its BLA, there were limited ORR data from Study 101 with substantial uncertainty regarding attribution of the response to omburtamab.

70. Study 101 patients received multi-modality CNS-directed anti-cancer therapy post-CNS relapse and prior to receiving omburtamab. Given these multiple pre-treatments, patients had minimal CNS disease at baseline prior to receiving omburtamab. Forty-seven of 48 patients (98%) with CSF cytology available had negative cytology at baseline. Furthermore 30 of 50 patients (60%) had no evidence of disease in the CNS per BICR.

71. Among 20 patients with imaging evidence of CNS/LM disease, only 4 had responses that were confirmed by an independent follow-up review, as required by RANO and EANON-ESMO guidelines.

72. FDA considers durability of response a critical component of response assessment and confirmation of response on follow-up imaging provides assurance regarding consistency of interpretation of response (which is particularly important when responses are difficult to assess, such as with LM metastases) and an assessment of the clinical importance of the response since transient responses are not likely to be meaningful.

73. Even among the 4 reported confirmed responses there were additional issues that limited their support of omburtamab's efficacy:

- 1 of 2 patients with parenchymal disease had no measurable target lesions, again limiting the ability to interpret the response data; additionally, the second reviewer did not identify any CNS/LM disease in this patient. The second patient with parenchymal disease also had LM disease per one reviewer but no evidence of CNS or LM disease by the second reviewer.

- Limited washout seen in two of the reported responders also affected the ability to interpret the results. Specifically, it was not possible to isolate the treatment effect of omburtamab from the other treatments. Two of 4 responders received radiation therapy within 30 days of their baseline One of the 2 patients who received radiation therapy within 30 days of their baseline scan also received chemotherapy within 21 days of their

baseline scan, ***which was a protocol violation per Study 101 exclusion criteria***.[3] This was compounded by receipt of chemotherapy or immunotherapy during the interval between the first scan demonstrating a reported response and the subsequent scan used for confirmation in 3 of 4 patients. This included two patients who received temozolomide, which is thought to have activity in patients with neuroblastoma and CNS relapse. This subsequent therapy limited the ability of these reported responses to be considered "confirmed" and the ability to attribute treatment effect to omburtamab.

- There was disagreement between the primary radiology reviewers in all cases, requiring adjudication. In two cases there was a major disagreement. This included one case with a reported partial response that the secondary reviewer reported as no evidence of disease at baseline and progressive disease at 5, 10, and 26 weeks. In another case with a reported complete response, the secondary reviewer reported no evidence of disease at baseline, 5 weeks, and 10 weeks and progressive disease at 26 weeks. Although these discrepancies were adjudicated, they provide further concerns regarding the reliability and reproducibility of the study results.

74. These factors introduce substantial uncertainty regarding attribution of the response to omburtamab, the accuracy of the response determinations themselves, or both.

75. ***Overall, no patient in Study 101 demonstrated an unequivocal treatment response that could be definitively attributed to omburtamab***.

V. FDA REPEATEDLY INFORMS Y-MABS THAT EXTERNAL CONTROL FROM CGCCR COULD NOT SUPPORT EFFICACY OF OMBURTAMAB BECAUSE IT WAS NOT "FIT FOR PURPOSE" AS A COMPARATOR

76. Prior to Y-mAbs initial BLA submission to facilitate the clinical development of omburtamab, FDA held multiple meetings with Y-mAbs.

77. During these meetings, FDA repeatedly expressed concerns that the CGCCR external control data may not be fit-for-purpose as a direct comparator for the overall survival data from patients in Study 03-133 because the patient populations may not have sufficient comparability for a valid comparison. FDA also repeatedly noted that – even if the CGCCR external control data were fit-for-purpose – direct evidence of the anti-tumor effect of omburtamab through assessment of overall response rate and duration of response as

[3] Data from Study 101 indicated that 68% of patients received anti-cancer therapy after omburtamab.

determined by a blinded independent radiology committee was needed to provide supportive evidence of the effectiveness of omburtamab.

78. As FDA later stated during the Advisory Committee meeting:

> ***Early on, we cautioned*** on the complexity of the proposed external control design ***and consistently highlighted*** that the ability to interpret the data would largely depend on the comparability of the populations and the ability to isolate the treatment effect of omburtamab from other therapies…***As we advised the applicant in prior meetings***, the receipt of so much intensive treatment prior to administration of omburtamab would be an important prognostic variable when matching to a control and ***would likely make it difficult to determine if any effects on survival are due to omburtamab and not to those treatments***. (emphasis added).

79. For example, during a December 9, 2016 meeting, FDA stated that "***additional data, including evidence of durable objective response, are necessary to provide the level of evidence needed to support approval***." FDA also stated that "there were ***important limitations to the data from Study 03-133*** such as the ***ability to isolate the treatment effect*** of omburtamab from other treatments for relapsed disease."[4]

80. On May 18, 2017, FDA told Y-mAbs that the data from 03-133 "***did not constitute substantial evidence of the safety and effectiveness required to support approval***."

81. During a June 14, 2017 meeting to discuss the design of Study 101, a multicenter trial intended to demonstrate that the results obtained by MSKCC could be reproduced by other sites, FDA stated that "the proposed study was inadequate to characterize the efficacy of omburtamab" and details were provided regarding expectations for a comparison external control to estimate efficacy of omburtamab.

82. Y-mAbs submitted the protocol for Study 101 on October 1, 2017.

[4] Unless otherwise noted, all quotations attributed to FDA from meetings with Y-mAbs are from FDA Briefing Document at 20-23, and Table2 and Table 3 and all emphases was added by FDA.

83. On December 19, 2017, FDA issued an Advice Letter advising Y-mAbs that "***the interpretation of time-to-event endpoints in Study 101 will be difficult as it is a single-arm trial.***" FDA stated that "***interpretation of the data will be dependent on variables*** such as the characterization of the external control, supportive data that confers anti-tumor activity (*e.g*. number of and duration of response), reproducibility between sites, toxicity and quality of the data collected."

84. On March 26, 2019, FDA again warned Y-mAbs "that time-to-event endpoints are difficult to interpret in the context of single-arm study," repeating that ***"[t]he interpretation of the data will be dependent on variables*** such as the characterization of the external control, supportive data that confers anti-tumor activity (*e.g*. number of and duration of response), reproducibility between sites, toxicity and quality of the data collected."

85. On September 11, 2019, a chemistry, manufacturing, and controls ("CMC") meeting was held to discuss product comparability data.

86. On November 19, 2019, FDA and Y-mAbs discussed clinical data that would be needed to support a BLA for omburtamab.

- "***FDA stated that there are important limitations to the data provided from Study 03-133 such as the inability to isolate the treatment effect of omburtamab from that of the other treatments administered for relapsed disease, that it is from a single-center, and that underlying differences in treatment or other diseases-specific factors of the populations from the German registry and those from MSKCC may impact outcomes***."
- "***FDA also stated the importance of response data from a blinded independent review to support the efficacy evaluation of a marketing application***."

87. On December 12, 2019, FDA issued an Advice Letter "reiterating that the ***interpretation of any endpoint is dependent on the quality of the data submitted to define the population treated in Study 03-133 and for the matched external controls.***"

88. During a February 25, 2020, pre-BLA meeting, FDA reiterated that "the ***interpretation of any endpoint is dependent on the quality of the data submitted to define the population treated in Study 03-133 and for the matched external controls.***"

89. On August 5, 2020, Y-mAbs submitted its initial BLA.

90. On October 2, 2020, FDA issued a Refusal to File letter, declining marketing approval of omburtamab, stating that the "***application did not contain substantial evidence consisting of adequate and well-controlled investigations that 131I-omburtamab is safe and effective for the treatment of pediatric patients with neuroblastoma that has relapsed to the CNS or LM***." FDA listed the following clinical reasons that the results of Study 03-133 did not support filing a BLA:

- The treatment effect of ^{131}I-Omburtamab cannot be objectively established or quantified based on the results from Study 03-133 compared to the reference rate derived from the CGCCR external control because there were no pre-specified statistical methods for matching analyses in place to assure comparability of the data from Study 03-133 to the CGCCR data. To provide a more accurate reference rate for 3-year overall survival (OS), ***data from Study 03-133 and the external control should be reanalyzed using a propensity score adjusted analysis (i.e. matching or IPTW) for important baseline characteristics*** (such as prior receipt of craniospinal irradiation) and prognostic factors (such as patient age and MYCN status). Additionally, to adequately interpret the analysis and ensure adequate event rate estimates***, it will be important for the external control data to reflect a patient population and follow-up to that is comparable to Study 03133***.

- Given the limitations associated with establishing and quantifying the treatment effect based on comparison of the 3-year OS rate observed in Study 03-133 to the 3-year OS rate derived from analyses of data from the CGCCR external control and from published literature, ***direct evidence of the anti-tumor effect of ^{131}I-Omburtamab through assessment of overall response rate and duration of response as determined by a blinded independent radiology is needed to provide supportive evidence of the effectiveness of ^{131}I-Omburtamab*** for the proposed indication.

VI. DEFENDANTS' FALSE AND MISLEADING STATEMENTS

91. On October 5, 2020 after the close of the securities markets, Y-mAbs issued a press release informing investors that it had received a RTF letter from FDA regarding its BLA for omburtamab for the treatment of neuroblastoma with CNS/LM relapse.

92. The press release stated, "[u]pon preliminary review, the FDA determined that certain parts of the Chemistry, Manufacturing and Control ("CMC") module and the Clinical module of the BLA ***require further detail. No additional non-clinical data have been requested or are required***."

93. The press release added that "***Y-mAbs is confident that it can address all points raised by the FDA***, including providing the requested additional CMC information and supplementary data from Study 101, which will include tumor response data from patients with evaluable disease among the first 24 patients included in the protocol."

94. The press release also stated that the "Company will request a Type A meeting with the FDA as soon as possible, and plans to work in close dialog with the Agency in order to amend the BLA with the goal of resubmitting the BLA before the end of 2020."[5]

95. On a conference call conducted on October 6, 2020, beginning at 9:00 a.m., Moller stated in prepared remarks, "the FDA determined that certain parts of the CMC module and the clinical module of the BLA required further detail to complete the review. No additional nonclinical data have been requested or are required. ***We remain confident that we can address all points raised by the FDA***…We plan to request a Type A meeting with the FDA within the next few weeks and plan to work in close dialogue with the agency in order to amend the BLA, with the goal of resubmitting the BLA before the end of 2020."

[5] According to FDA guidance, a Type A meeting is "A meeting which is necessary for an otherwise stalled drug development program to proceed (previously referred to as a "special considerations" meeting)." Industry Meeting Type | FDA.

96. The very first question from analysts – asked by Alec Warren Stranahan (BofA Merrill Lynch) – was, "[a]re you surprised by the FDA's determination, given the extent of prior dialogue leading up to the BLA? ***Are these new issues being raised that hadn't been discussed previously?***" Moller stated unequivocally ***"yes, I was very surprised and of course, disappointed***."

97. In response to another question, Moller volunteered, "[w]e're going to meet with them as soon as we can for the Type A meeting. ***We are going to rectify this***. We're going to resubmit. And we'll get the product out to the kids, so they can get help from it."

98. Moller also stated, "***[FDA] really want to emphasize that they want to work with us on getting this successfully refiled and approved as quickly as possible.***"

99. The same analyst then asked, "[a]nd then on new time lines, what impact do you think this will have on the timing of approval? And when could we expect commercialization? Is this sort of the back half '21 timing now?" Moller again stated, "***Yes…shortly after the Type A meeting, we should be ready to put together the documents for refiling the BLA***," stating that he estimated that the refiling of the BLA would occur on January 5, 2021.

100. Moller added later on that call that:

> They requested 2 things. One thing was a different type of statistical comparison between the data from Study 03-133 and the old study with more than 100 patients and the historical controls. ***It's not a problem***. We can do it, and we already started working on that this week. The other thing they specifically requested was tumor response data for patients from Study 101, where the tumor responses has been independently evaluated according to the RANO criteria for measuring tumor responses in the central nervous system.
>
> * * *
>
> ***So very clear, and we have everything, and I have no concern that the FDA will think, "Oh, that is not sufficient response." I think we are beyond that also***.

101. In closing, Moller stated, "***this is a minor setback***."

102. Also on October 6, 2020, Y-mAbs filed a Form 8-K with the SEC, which attached the October 5, 2020 press release as Exhibit 99.1. The Form 8-K was signed by Gad.

103. The statements referenced in ¶¶92-102 were materially false and misleading because the deficiencies identified by FDA in the RTF letter and related communications were not a "surprise" and were not non-substantive requests for additional information that were merely a "minor setback" that "[i]s not a problem" and which Y-mAbs could "rectify" by the end of 2020 such that there was "no concern that the FDA will think, 'Oh, that is not sufficient response'" because FDA "want to work with us on getting this successfully refiled and approved as quickly as possible." Defendants knew or recklessly disregarded but failed to disclose that (i) FDA had determined that the "application did not contain substantial evidence consisting of adequate and well-controlled investigations that 131I-omburtamab is safe and effective"; (ii) Y-mAbs would have difficulty addressing FDA's concerns, if possible at all, because the "statistical methods for matching analyses" were not "pre-specified" and the patient populations and treatment regimens for patients in Study 03-133 and CGCCR were not "comparable"; and (iii) FDA had met with and corresponded with Y-mAbs throughout 2017 to 2020, and had repeatedly advised Y-mAbs of its concerns that (a) the patient population in Study 03-133 was not comparable to the population in CGCCR, (b) the receipt of so much intensive treatment prior to administration of omburtamab by patients in Study 03-133 "would likely make it difficult to determine if any effects on survival are due to omburtamab and not to those treatments," (c) even if the two populations were "fit-for-purpose" direct evidence of the anti-tumor effect of omburtamab as determined by a blinded independent radiology committee would be needed to demonstrate efficacy, (d) interpretation of Study 101 would be "difficult" because it was a "single-arm trial" and (e) no patient in Study 101 demonstrated an unequivocal treatment response that could be definitively attributed to omburtamab.

104. Analyst reports published immediately following Defendants' statements demonstrate that even the most sophisticated investors were misled by Defendants. For example, on October 6, 2020 Boris Peaker of Cowen (who was on the October conference call), issued a report with an "Outperform" rating, stating

> No additional non-clinical data have been requested or are required. … The company will now prepare the CMC process validation documentation and anticipate completion by November. The company will then request a Type A meeting with the FDA and anticipate re-submission by late-20/early-21. We believe the data requested is readily available and as such, there is no material risk with the refuse to file letter, and still anticipate approval and launch in late-21.

105. Guggenheim similarly issued a "Buy" report stating:

> **Key Message**: After the close, YMAB announced that the FDA issued a Refusal to File (RTF) letter for the BLA for omburtamab…, noting the FDA's request for additional detail in the CMC and clinical module. We spoke with mgmt ahead of its conference call tomorrow and came away encouraged that the RTF is only a minor setback to omburtamab given (1) no requirements for additional trials or patient recruitment; & (2) requests are for data in hand. YMAB's goal to re-file its BLA by YE20 could push out our assumptions 3-6 months but has no impact on our fundamental thesis for the stock.

106. On November 3, 2020, a Type A meeting was held with Y-mAbs to discuss the proposed plan to address filing issues described in the RTF letter. At that meeting, again the "FDA expressed concern that the ***CGCCR external control data may not be fit-for-purpose*** as a direct comparator for the overall survival data from patients in Study 03-133 in that the patient populations may not be comparable. Specifically, ***there appears to be an imbalance in receipt of radiation*** treatment (more patients in the Study 03-133 received radiation, specifically craniospinal irradiation [CSI], compared to the patients in the CGCCR external control where no patients received CSI). FDA stated that given the uncertainties regarding the interpretation of overall survival results in Study 03-133, a single-arm study, ***response data are needed*** to support the antitumor effect of ^{131}I-omburtamab."

107. Notwithstanding the skepticism reflected in FDA's comments at the November 3, 3020 meeting, in Y-mAbs's earnings call for the third quarter of 2020, conducted on November 6, 2020, Gad stated, "***We are also expecting to resubmit the omburtamab BLA late 2020 or in the beginning of 2021***." Moller further stated that "***Y-mAbs is confident that it can address all points raised by the FDA***," and:

> [I]t's pretty clear that on the Chemistry, Manufacturing, and Controls ***we have resolved all the issues that they have requested*** and we are ready to put that together in a resubmission package.

108. The statements referenced in ¶107 were materially false and misleading for the reasons identified in ¶103(i)-(iii), and based on FDA's comments during the November 3, 2020 meeting, it was not "clear" that Y-mAbs had "resolved all the issues identified by the FDA" and that Y-mAbs would be permitted to resubmit the BLA by late 2020 or the beginning of 2021. Defendants knew or recklessly disregarded but failed to disclose that FDA had warned that "the CGCCR external control data may not be fit-for-purpose as a direct comparator for the overall survival data" and that "the patient populations may not be comparable" because, among other things, "there appears to be an imbalance in receipt of radiation treatment…specifically craniospinal irradiation."

109. Moller also stated, "In addition, an oral presentation at SIOP, Dr. Kim Kramer from MSK presented interim results for 17 patients enrolled in the company's pivotal 101 multicenter study. The study showed a 12-month overall survival rate of 87% with a median follow-up of 26 weeks. ***This compares very favorably to an OS of approximately 30% in a historical control group***. ***The preliminary overall survival data results from the multicenter study 101 are encouraging and appears almost identical to the results of Study 03-133, which was conducted at the Memorial Sloan Kettering***."

110. The statements referenced in ¶109 were materially false and misleading for the reasons identified in ¶103(i)-(iii) and because the Defendants knew or recklessly disregarded but failed to disclose that FDA had repeatedly warned that "the CGCCR external control data may not be fit-for-purpose as a direct comparator for the overall survival data" and that "the patient populations may not be comparable" because, among other things, "there appears to be an imbalance in receipt of radiation treatment…specifically craniospinal irradiation."

111. On January 7, 2021, FDA again told Y-mAbs "***the CGCCR external control was not fit-for-purpose due to lack of granular patient-level data***"

112. On January 8, 2021, in light of the CGCCR data not being "fit-for-purpose," a teleconference was held with Y-mAbs "to discuss external control data that could serve as direct comparator to data in Study 03-133 and response data in Study 101." During that teleconference:

- "FDA referenced communication to Y-mAbs from 1/07/2021 which expressed ***concern that the CGCCR external control was not fit-for-purpose due to lack of granular patient-level data***."
- "FDA acknowledged that Y-mAbs had attempted to identify other sources including Children's Oncology Group and SIOPEN and that data on post-CNS relapse was not available."
- "Due to the difficulties associated with obtaining patient-level data that would be of sufficient quality and granularity to serve as an appropriate external control, Y-mAbs expressed a preference for pursuing a clinical development strategy based upon demonstration of durable overall responses in patients with measurable disease enrolled in Study 101."

113. On February 17, 2021, Y-mAbs filed a Prospectus with the SEC for the secondary offering of 2,439,025 shares of Y-mAbs common stock at $41.00 a share. According to Y-mAbs's first quarter Form 10-Q, filed with the SEC on May 6, 2021, 2,804,878 shares were sold on the secondary offering at a price of $41.00 per share. The underwriters exercised the full over-allotment option of 365,853 shares.

114. On February 26, 2021, Y-mAbs held its earnings call for the fourth quarter of 2020. Gad stated on the call that Y-mAbs had had several interactions with FDA and further that a Type B meeting with FDA had been scheduled for March 26, 2021.[6]

115. Moller, on the fourth quarter earnings call, stated:

> We have maintained a very close dialog with the FDA regarding the resubmission of the Omburtamab BLA, and have scheduled a Type B meeting next month, where we hope to reach a final agreement with the agency on the remaining details before initiating our rolling resubmission for Omburtamab BLA. ***We remain confident that we can address all points raised by the FDA***, including providing the requested supplementary data from Study 101.

116. The statements referenced in ¶115 were materially false and misleading for the reasons identified in ¶103(i)-(iii) and because Defendants knew or recklessly disregarded but failed to disclose that FDA had recently reiterated the concern (i) that "the CGCCR external control was not fit-for-purpose due to lack of granular patient-level data," (ii) the CGCCR external control data may not be fit-for-purpose as a direct comparator for the overall survival data" and that "the patient populations may not be comparable" because, among other things, "there appears to be an imbalance in receipt of radiation treatment…specifically craniospinal irradiation," and (iii) that Y-mAbs had failed to find a substitute external control population.

117. During the February 26, 2021 earnings call, Moller also stated:

> ***One of the things that happened in December was there was a new paper published by SIOPEN***, the European Pediatric Oncology Organization, where they gave data from 63 patients with CNS/leptomeningeal medulloblastoma relapse and shared overall survival data that is precisely as [Rudden and Torres] as for all the other studies that has been published.
>
> ***The good thing here is that there are some more granularity and details on that database*** than there was available initially from the central German cancer

[6] According to FDA guidance, the purpose of a Type B meeting is "to acquaint FDA reviewers with the general information to be submitted in the marketing application, discuss appropriate methods for statistical analysis, discuss proposed format for data in the planned marketing application, to identify those studies that the sponsor is relying on as adequate and well-controlled, and to discuss any major unresolved problems (21 CFR 312.47)." Industry Meeting Type | FDA.

> registered database. ***So now we have 2 sets of historical controls.*** We have worked with SIOPEN in January to make sure and agree with them that they would give us access to the data from that study, and we have gotten access to that, ***which the FDA seems to be very happy about***.
>
> So now we have used that data set also as second or third historical control panel.

118. The statements referenced in ¶117 were materially false and misleading for the reasons identified in ¶116 and because Defendants knew or recklessly disregarded but failed to disclose that FDA had acknowledged that Y-mAbs had attempted to identify other sources including SIOPEN but "data on post-CNS relapse was not available" and FDA had again "expressed concern that the CGCCR external control was not fit-for-purpose due to lack of granular patient-level data."

119. On March 26, 2021, a Type B meeting was conducted "where FDA again expressed concern that insufficient information was provided to determine whether the data from CGCCR are fit-for-purpose for establishment of a robust external comparator and outlined specific deficiencies." At that meeting, FDA stated that "***if ultimately FDA cannot determine if the patient populations are similar enough or if the sample size derived from the external control data is too small to make statistical comparisons, an alternative clinical development program will need to be discussed***." Additionally, "FDA stated that given the uncertainty regarding the interpretability of overall survival results in Study 03-133, a single-arm study, ***compelling response data will likely be needed to support the anti-tumor effect of ^{131}I-Omburtamab, even if FDA determines that the data from the CGCCR external control are fit-for-purpose***."

120. On May 7, 2021, Y-mAbs held its Q1 2021 earnings call. During the call, Gad stated, "Further, we gave an update on omburtamab in the U.S. and also our Type B meeting with the FDA on March 26 and here we are continuing to working hard towards being able to ***resubmit the BLA for omburtamab late in this second quarter or in the third quarter of this***

year." Moller stated, "We are maintaining a very close and open dialog with the FDA regarding the resubmission and have scheduled a second Type B meeting on June 1, where we hope to ***reach final agreement with the agency*** on the remaining details concerning this granularity of the data from our identified historical control groups and how we would work forward with this.

121. On June 1, 2021, another Type B meeting was conducted where FDA stated that given the complexity of this external control study design and the uncertainty introduced by the retrospective use of historical data to design an external control arm to appropriately isolate the treatment effect as well as multiple prior looks at the data sources,

- "The review of a marketing application supported by the proposed comparative analysis will be based on FDA's overall assessment of the results of multiple analyses, including analyses of the pre-specified primary and secondary endpoints in addition to sensitivity analyses."

- "***FDA's determination regarding whether substantial evidence of effectiveness has been demonstrated will not rely solely on the results of a single analysis*** of the primary efficacy endpoint or based on a single population."

122. On June 23, 2021, Y-mAbs issued a press release stating that it had recently concluded a Type B meeting with FDA regarding omburtamab and that "[b]ased on our discussions with the FDA, we believe ***we now have a clearer path towards the resubmission of the omburtamab BLA to the FDA***" Notwithstanding FDA's continuing skepticism that it would approve omburtamab, Moller reiterated in the June 23, 2021 press release that "***We are very pleased to be aligned with the FDA on the next step towards the resubmission of the Omburtamab BLA***...."

123. The statements referenced in ¶122 were materially false and misleading because the Defendants implied that the prospects of approval of omburtmab had improved since the RFT letter and that FDA and Y-mAbs had agreed on what was necessary for a successful submission when, in fact, FDA had expressed serious concerns about the data and notified Y-

mAbs that it would be applying more stringent analyeses, and Defendants knew or recklessly disregarded but failed to disclose that (i) FDA had repeatedly warned that "the CGCCR external control was not fit-for-purpose due to lack of granular patient-level data," (ii) the CGCCR external control data also "may not be fit-for-purpose as a direct comparator for the overall survival data" and that "the patient populations may not be comparable" because, among other things, "there appears to be an imbalance in receipt of radiation treatment…specifically craniospinal irradiation", (iii) FDA's determination regarding whether substantial evidence of effectiveness has been demonstrated will not rely solely on the results of a single analysis of the primary efficacy endpoint or based on a single population, (iv) the review of a marketing application supported by the proposed comparative analysis will be based on FDA's overall assessment of the results of multiple analyses, including analyses of the pre-specified primary and secondary endpoints in addition to sensitivity analyses, (v) if ultimately FDA cannot determine if the patient populations are similar enough or if the sample size derived from the external control data is too small to make statistical comparisons, an alternative clinical development program would be needed, and (vi) "compelling response data" would be necessary to support the anti-tumor effect of omburtamab, even if FDA determines that the data from the CGCCR external control are fit-for-purpose.

124. Based on Defendants' misstatements, analysts continued to believe that approval of omburtamab was a certainty. On June 23, 2021, J.P. Morgan issued a report stating, "[i]mportantly, the anticipated regulatory path seems to be more clearly outlined, and the company has aligned with the FDA on the next step forward. Even though today's update does come with a minor delay for the expected resubmission (~3-6 months), ***we maintain our view that there is a high probability of an ultimate approval, given what appears to be a high level***

of regulatory engagement, clear unmet need, and favorable view of the data the company has generated."

125. On June 23, 2021, Wedbush issued a "Outperform" rating, stating, "While this is a short pushback from the company's original guidance, we are pleased to see YMAB make progress with the FDA and provide a reasonable timeline for the BLA resubmission. We anticipate a positive pre-BLA meeting outcome and an eventual FDA approval."

126. On September 14, 2021, a Type B meeting was held at which "FDA expressed outstanding concerns regarding the datasets, definitions and derivations of the variables. ***FDA also stated that they will not be able to rely on a single population or primary analysis and will consider the totality of evidence*** from several sensitivity analyses to objectively quantify the treatment effect."

127. On November 5, 2021, Y-mAbs held its November 5, 2021 earnings call for the third quarter of 2021. During opening remarks, Gad reassured investors that "***the resubmission of the omburtamab BLA is progressing well***." Moller stated:

> Based on feedback from the FDA at a Type B meeting in September, where we provided the FDA with additional detailed data and statistical analysis plan, we have recently requested a pre-BLA meeting. And we believe we are positioned to complete the submission during the course of the first quarter 2022, potentially allowing for FDA approval of Omburtamab in the fourth quarter of 2022. Needless to say, we are very ***pleased to be aligned*** with the FDA on the next steps.

128. The statements referenced in ¶127 were materially false and misleading for the reasons identified in ¶123, and because Defendants knew or recklessly disregarded but failed to disclose that FDA had reiterated its "outstanding concerns regarding the datasets, definitions and derivations of the variables," which Y-mAbs had failed to address during their communications.

129. On December 15, 2021, Y-mAbs held it Research and Development Day. During the presentation, which Raja and Gad also attended, Moller stated, "So we have a pre-BLA meeting coming up shortly in January. And after that meeting, ***we expect to get a green light*** …I think we have put together a very strong package that ***should satisfy the concerns the FDA raised at the refused file and that they have also raised during our discussions***."

130. The statements referenced in ¶129 were materially false and misleading for the reasons identified in ¶123, and because Defendants knew or recklessly disregarded but failed to disclose that FDA had reiterated its "outstanding concerns regarding the datasets, definitions and derivations of the variables," which Y-mAbs had failed to address during their communications.

131. On January 13, 2022, a pre-BLA Type B meeting was held "to discuss the plan to resubmit BLA 761176 based on the efficacy analyses using a propensity score model to evaluate OS in Study 03-133 compared with the external control group." At that meeting:

- "***FDA stated that there was insufficient information to provide agreement on the efficacy package to support the BLA.***"
- "FDA stated that the ability to satisfactorily audit the CGCCR external control database for the external control cohort would be a filing issue."
- "FDA noted that the assessment of responses in Study 101 appear to be limited by the washout period from prior therapies relative to the timing of the baseline scans, and the timing of onset of response following ^{131}I-Omburtamab."

132. During the course of discussions with FDA, Y-mAbs proposed an estimand for causal effect estimation of average treatment effect on the treated (ATT) by weighting. Due to the imbalance in sample size, Y-mAbs proposed down-weighting of the external control arm. Y-mAbs also proposed trimming of large weights (>5) for stabilization. ***FDA communicated to Y-mAbs that the proposed down-weighting of the external control arm "appeared arbitrary."***

133. On February 11, 2022, Y-mAbs issued a press release announcing completion of a pre-BLA meeting with FDA for omburtamab. Gad is quoted stating in the press release that ***"[w]e are pleased with the outcome of the pre-BLA meeting for Omburtamab providing a clear regulatory path forward for the resubmission of the BLA***." In the same press release, Moller stated, "***[w]e believe that we can resubmit the Omburtamab BLA by the end of the first quarter of 2022***."

134. The statements referenced in ¶133 were materially false and misleading for the reasons identified in ¶123, and because Defendants knew or recklessly disregarded but failed to disclose that (i) FDA had reiterated its "outstanding concerns regarding the datasets, definitions and derivations of the variables" during the September 14, 2021 and January 13, 2022 meetings, which Y-mAbs had failed to address during their communications, (ii) FDA stated at the January 13, 2022 meeting that "there was insufficient information to provide agreement on the efficacy package to support the BLA," (iii) FDA stated that "the ability to satisfactorily audit the CGCCR external control database for the external control cohort would be a filing issue," (iv) FDA stated that "assessment of responses in Study 101 appear to be limited by the washout period from prior therapies relative to the timing of the baseline scans, and the timing of onset of response following ^{131}I-Omburtamab," and (v) FDA had determined that Y-mAbs' "proposed down-weighting of the external control arm appeared arbitrary."

135. Based on Defendants' misstatements, analysts continued to believe that approval of omburtamab was a certainty. For example, Bank of America issued a research report on February 11, 2022, with a "Buy" rating, stating "We have maintained a 100% likelihood of approval for omburtamab in its initial indication in our model, underscoring our continued confidence in its ultimate approval…."

136. Cowen also issued a report on February 11, 2022, stating "We view shares as undervalued for the potential of omburtamab and Danzyelza…We are encouraged that Y-mAbs completed its pre-BLA meeting with the FDA as planned and that guidance on the resubmission timeline was maintained. Given that the company anticipates a resubmission by the end of Q1, we expect that the completion of the application is relatively straightforward…Submission of the BLA should remove an overhang for shares. We look forward to continued progress and remain Outperform."

137. On February 25, 2022, Y-mAbs held their earnings call for the fourth quarter of 2021. Gad stated, "***The resubmission of omburtamab BLA is progressing as planned***. We held a pre-BLA meeting with the FDA in January, ***which confirmed our path towards a BLA resubmission in March***." Moller stated:

> Needless to say we are very pleased to be ***aligned with the FDA on the next step*** and believe that if approved, Omburtamab will be a significant benefit to patients with central nervous system/leptomeningeal metastases from neuroblastoma.

138. During the earnings call, a Bank of America Securities analyst asked, "Could you just talk to any remaining list items you maybe need to check off in the FDA's view or the tumor response data and the CMC discussion you provided, sufficient for them?" Moller responded,

> To the best of my understanding, ***all the information that we need, we have***. And what we are doing right now is we are finalizing what's called final study reports on -- thanks to actually complete the clinical section and the safety section of the BLA filing. So there's no -- we're not waiting for additional stuff to come in. There's some discussion. The FDA wants to understand how they can actually -- to which degree they can verify the historical control data in the central German cancer registry in Cologne, but ***that's not something that is holding up the submission of the BLA filing***.

139. The statements referenced in ¶¶137-138 were materially false and misleading for the reasons identified in ¶123, and because Defendants knew or recklessly disregarded but failed to disclose that (i) FDA had reiterated its "outstanding concerns regarding the datasets,

definitions and derivations of the variables" during the September 14, 2021 and January 13, 2022 meetings, which Y-mAbs had failed to address during their communications, (ii) FDA stated at the January 13, 2022 meeting that "there was insufficient information to provide agreement on the efficacy package to support the BLA," (iii) FDA stated that "the ability to satisfactorily audit the CGCCR external control database for the external control cohort would be a filing issue," (iv) FDA stated that "assessment of responses in Study 101 appear to be limited by the washout period from prior therapies relative to the timing of the baseline scans, and the timing of onset of response following ^{131}I-Omburtamab," and (v) FDA had determined that Y-mAbs "proposed down-weighting of the external control arm appeared arbitrary."

140. On March 25, 2022, "Y-mAbs provided additional detail regarding the audit process for the CGCCR external control dataset" to FDA and "stated they welcomed the opportunity to discuss the proposal in a teleconference the following week."

141. On March 29, 2022, the "FDA thanked Y-mAbs for the response and agreed to follow up within 30 days."

142. Two days later, on March 31, 2022, despite previously repeatedly telling investors that it would not resubmit the BLA until they "reach a final agreement with the agency on the remaining details" and "get a green light," Y-mAbs did not await any response from FDA, instead electing to resubmit the BLA prior to reaching agreement with FDA on the content of the application. Indeed, as discussed above, FDA had recently stated "there was insufficient information to provide agreement on the efficacy package to support the BLA" and FDA had determined that Y-mAbs "proposed down-weighting of the external control arm appeared arbitrary."

143. On April 1, 2022, Y-mAbs issued a press release, stating that the Company had completed the resubmission of its BLA for omburtamab. Gad was quoted in the press release as

stating that "I am excited to see the completion of Y-mAbs' second BLA submission in neuroblastoma."

144. The statements referenced in ¶143 were materially false and misleading for the reasons identified in ¶139 and because Defendants knew or recklessly disregarded but failed to disclose that Y-mAbs had resubmitted its BLA for omburtamab "prior to reaching agreement with the FDA on the content of the application" and despite FDA stating "that there was insufficient information to provide agreement on the efficacy package to support the BLA" and that Y-mAbs' "proposed down-weighting of the external control arm appeared arbitrary."

145. Based on Defendants' misstatements, analysts continued to be misled. Cowen issued an analyst report on April 1, 2022, stating "Y-mAbs announced that the company successfully resubmitted the BLA for omburtamab in the treatment of pediatric patients with CNS/leptomeningeal metastasis on March 31, ***just meeting the company's most recent Q1 resubmission guidance***. Given the company's repeated interactions with the FDA, today's news should provide some relief for investors."

146. Guggenheim also issued a report on April 1, 2022, stating: "Key Message: This morning, YMAB announced completion of omburtamab BLA refiling on 3/31, ***consistent with prior guidance***. This event partially addresses an ongoing regulatory overhang on the omburtamab program, which previously received a refusal-to-file (RTF) in 4Q 2020 as FDA requested additional data on an ongoing clinical study and had questions on CMC + a synthetic historical control arm."

147. On April 27, 2022, Y-mAbs issued a press release stating that Moller had stepped-down as CEO and that Gad would replace Moller as interim CEO. As part of that transition, Gad would cease being Board Chairman, but would remain a member of the Y-mAbs Board.

148. On May 10, 2022, in introductory remarks for the first quarter 2022 conference call, Gad stated that Y-mAbs "saw a great start to 2022 ... notably the resubmission of the BLA for omburtamab in Q1, ***as promised***."

149. Gad added on the call that:

> We are thrilled with our recent resubmission of the omburtamab BLA for the treatment of CNS/leptomeningeal metastases for neuroblastoma. As you might recall, ***we had the pre-BLA meeting with the FDA in January of this year and confirmed our path towards our March BLA resubmission, which we ultimately achieved***. We are hopeful that omburtamab will be approved ***given the meaningful improvements in overall survival rate***, which data has significantly matured with time.

150. The statements referenced in ¶¶148-149 were materially false and misleading for the reasons identified in ¶144.

151. On August 9, 2022, Y-mAbs held its earnings call for the second quarter of 2022. Gad stated on the call that ***"[w]e are optimistic about the potential approval based on meaningful improvement in overall survival rates and unparalleled efficacy in patients with CNS metastases from neuroblastoma***."

152. Defendant Rajah, Y-mAbs's Chief Medical Officer, stated on the call (id. at 10-11) that:

> [T]he headline news around efficacy concludes that ***there is a clear benefit -- clinical benefit in terms of response rates and survival*** with a manageable safety profile. For example, in the 03-133, where, as you know, we looked at the overall survival, progression-free survival and ***we did an indirect comparison with an external control arm to serve as an appropriate comparator***. ***Preliminary data has shown that the overall survival difference doing the indirect comparison the need in overall survival has a difference of roughly 15 months in the control arm versus 43 months in the actual interventional arm, albeit taking to account these are indirect comparisons***.
>
> Moving to the 101 study, where the primary endpoint was response rates. Here, the primary aim is to look at individual patients, looking at response rate at 6 months after initiation of treatment. Here, ***we have shown certainly in those patients with measurable disease, which is about 20 patients. Roughly 14***

> ***patients had a level of disease control, which includes complete response, partial response as well as stable disease.***
>
> So I think combined with these 2 studies, we believe that there is clearly a signal of clinical benefit for these patients who really have no alternative treatments, with a very poor prognosis.
>
> * * *
>
> And I should add that all of these points we have been involved in a number of discussions – ongoing discussions with the FDA. And ***the team are confident we are able to address these, not just the clinical arguments, but also the statistical arguments with a high degree of confidence***.

153. The statements referenced in ¶¶151-152 were materially false and misleading for the reasons identified in ¶144.

VII. THE TRUTH EMERGES

154. On October 26, 2022, shortly after the market opened, FDA publicly released its Briefing Document for the Oncologic Drugs Advisory Committee Meeting scheduled for October 28, 2022.

155. In the Briefing Document, FDA concluded that "s "difference in survival cannot be reliably attributed to omburtamab," and identified three key issues with the application submitted by Y-mAbs: "(1) The external control population is not fit-for-purpose as a comparator due to substantive differences between the study and control populations that limit the ability to attribute survival differences to the effect of Omburtamab; (2) recognizing the level of evidence provided and need for regulatory flexibility, FDA performed additional analyses to examine bias and results reinforce that differences in survival cannot be reliably attributed to Omburtamab; (3) the application does not include reliable response rate data to provide supportive evidence of the treatment effect of Omburtamab." Specifically, the Briefing Document identified the deficiencies discussed in Sections III and IV above.

156. The Briefing Document highlighted the fact that FDA had repeatedly warned Y-mAbs over the course of years that the CGCCR external control data was not "fit-for-purpose" as a direct comparator because of significant differences in the patient population and treatments:

> FDA met with Y-mAbs multiple times to discuss the issues outlined in the RTF letter and to reach agreement on how to address each issue. ***FDA repeatedly expressed concerns that the CGCCR external control data may not be fit-for-purpose as a direct comparator for the overall survival data from patients in Study 03-133 because the patient populations may not have sufficient comparability for a valid comparison***. ***FDA also repeatedly noted that direct evidence of the anti-tumor effect of 131I-omburtamab through assessment of overall response rate and duration of response as determined by a blinded independent radiology committee is needed to provide supportive evidence of the effectiveness of 131I-omburtamab***.[7]

Indeed, FDA included two tables (Table 2 and Table 3) summarizing the numerous communications with Y-mAbs in which FDA's warned Y-mAbs about using CGCCR data as an external control and that "***compelling response data*** will likely be needed [from Study 101] to support the anti-tumor effect" of omburtamab, even if FDA determined that the data from the CGCCR external control were fit-for-purpose. Further emphasizing the fact that FDA had made it crystal clear that the submission would be deficient to demonstrate efficacy, FDA even repeated **bolded** certain communications in which it had warned Y-mAbs of the deficiencies.[8]

157. The Briefing Document also emphasized that Y-mAbs never received approval from FDA to resubmit the BLA, stating "[o]n March 31, 2022, Y-mAbs elected to resubmit the BLA on March 31, 2022 prior to reaching agreement with the FDA on the content of the application."[9]

158. An October 26, 2022 Cowen analyst report recognized that Defendants had previously misrepresented the degree of FDA's acceptance of Y-mAbs's submissions:

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[7] FDA Briefing Document at 20 (emphasis added).
[8] *See id*. at 21-23.
[9] *Id*. at 20.

> Given the number of interactions the company had with the FDA prior to the BLA resubmission in March…, we were optimistic for a favorable outcome from the regulatory review. Given the FDA's document today, it appears as though the Agency continued to have concerns at each meeting and YMAB resubmitted the application "prior to reaching agreement with the FDA on the content of the application with respect to the plan for audit of the external control data and information submitted regarding the type of doses of CS-directed radiation therapy." While the Agency agreed to review the application, the briefing documents raised several potential issues, and thus it appears YMAB will face a challenge to convince the committee to vote for approval on Friday.

159. A Canaccord Gnuity LLC analyst report similarly stated "Our 90% likelihood of approval in Omblastys' initial indication is now clearly aggressive, and was based on a comparison of the drug's median survival in comparison to external controls. Following FDA's analysis, the omburtamab study arm and the external control arm are less comparable than we had assumed."

160. A J.P. Morgan analyst recognized:

> Overall, it does not appear that the agency's posture on the data thus far has changed since the Refuse to File in October 2020, where the FDA had determined that certain parts of the CMC and Clinical modules of the BLA required further detail, and later requested additional data from Y-mAbs following the identification of historical control groups in March 2021.
>
> …
>
> ***It also gives us pause that there was not go-ahead on the totality of the content in the resubmitted BLA***. The briefing documents also note that "Y-mAbs elected to resubmit the BLA prior to reaching agreement with the FDA on the content of the application with respect to the plan for audit of the external control data and information submitted regarding the type and dose of CNS-directed radiation therapy."

161. A BMO Capital Markets analyst observed that the views of FDA identified in the Briefing Document "introduce[e] unanticipated risks to approval…"

162. Y-mAbs's stock price fell $4.16 per share on October 26, 2022 (from $15.17 to $11.01) as a result of the revelations of true facts in FDA's Briefing Document. Trading volume was extraordinarily high at 2.1 million shares.

163. As news of FDA's Briefing Document spread and the market digested the information, Y-mAb stock continued its rapid decline. On October 27, 2022, Y-mAbs common stock declined by an additional $2.16 per share on October 27, 2022 (from $11.01 to $8.85). Y-mAbs shares were trading at $8.93 on October 28, 2022 when trading was halted for the Advisory Committee.

164. On Friday, October 28, 2022, after the close of trading, Y-mAbs filed a Form 8-K with the SEC. The Form 8-K informed investors that the AdCom had voted unanimously 16 to 0 that Y-mAbs had not provided sufficient evidence to conclude that omburtamab improved overall survival. The grounds for denial were precisely the same grounds that Y-mAbs was apprised of by FDA during their 2020 bid for BLA approval as follows:

> These review issues result in a large degree of uncertainty regarding whether the observed differences in overall survival between the Study 03-133 and external control populations are due to Omburtamab or whether they are due to differences in other anticancer treatment, supportive care regimens, unknown differences between the two populations, or a combination of these factors.

165. During the Advisory Committee meeting, FDA stated:

> ***Early on, we cautioned*** on the complexity of the proposed external control design ***and consistently highlighted*** that the ability to interpret the data would largely depend on the comparability of the populations and the ability to isolate the treatment effect of omburtamab from other therapies…***As we advised the applicant in prior meetings***, the receipt of so much intensive treatment prior to administration of omburtamab would be an important prognostic variable when matching to a control and ***would likely make it difficult to determine if any effects on survival are due to omburtamab and not to those treatments***.

166. Y-mAbs common stock closed on Monday, October 31, 2022, in the aftermath of disclosure of the true facts occasioned by the release of the Briefing Document and the Advisory Committee hearing and vote, at $3.61.

VIII. ADDITIONAL ALLEGATIONS OF SCIENTER

167. By virtue of Y-mAbs's meetings with FDA, Defendants had actual knowledge that FDA would not approve the BLA for omburtamab without the demonstration of substantial

evidence of effectiveness through adequate and well-controlled studies. As summarized by FDA in its Briefing Document (at 20):

> FDA met with Y-mAbs multiple times to discuss the issues outlined in the RTF letter and to reach agreement on how to address each issue. FDA repeatedly expressed concerns that the CGCCR external control data may not be fit-for-purpose as a direct comparator for the overall survival data from patients in Study 03-133 because the patient populations may not have sufficient comparability for a valid comparison. FDA also repeatedly noted that direct evidence of the antitumor effect of ^{131}I-Omburtamab through assessment of overall response rate and duration of response as determined by a blinded independent radiology committee is needed to provide supportive evidence of the effectiveness of ^{131}I-Omburtamab.
>
> On March 31, 2022, Y-mAbs elected to resubmit the BLA prior to reaching agreement with the FDA on the content of the application.

168. During the Advisory Committee meeting, FDA stated:

> ***Early on, we cautioned*** on the complexity of the proposed external control design ***and consistently highlighted*** that the ability to interpret the data would largely depend on the comparability of the populations and the ability to isolate the treatment effect of omburtamab from other therapies…***As we advised the applicant in prior meetings***, the receipt of so much intensive treatment prior to administration of omburtamab would be an important prognostic variable when matching to a control and ***would likely make it difficult to determine if any effects on survival are due to omburtamab and not to those treatments***.

169. Defendants' knowledge (*i.e.* scienter) of Y-mAbs communications with FDA concerning the BLA can be inferred because these facts were critical to Y-mAbs core operations. Y-mAbs described omburtamab as its "lead product candidate" and regularly touted it to investors.

170. Defendants' scienter can further be inferred because Defendants regularly spoke in detail about the communications with FDA regarding the BLA as well as the results of Study 03-133 and Study 101.

171. Defendants were financially motivated to misrepresent the truth and artificially inflate the market price of Y-mAbs stock. Among other things, during the Class Period, Y-

mAbs conducted a secondary offering on February 17, 2021 – selling 2,804,878 million shares of YMAB common stock at $41.00 per share, for gross proceeds of $115 million.

172. From 2019 through the first quarter of 2022, Gad realized gross proceeds of $ $43.0 million from sales of Y-mAbs common stock on the open market. In the first quarter of 2022 alone, Gad realized gross proceeds of $7.0 million from insider sales to satisfy a margin loan.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

173. Plaintiff brings this action as a class action pursuant to Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of all persons or entities who purchased shares of Y-mAbs common stock on the open market, or pursuant to Registration Statements filed with the SEC, during the Class Period of October 6, 2020 through October 28, 2022, inclusive, and suffered damages caused by Defendants' violations of the federal securities laws (the "Class"). Excluded from the Class are the Defendants herein, officers and directors of Y-mAbs ("Excluded D&Os"), members of the Defendants' and the Excluded D&A's immediate families, affiliates of Y-mAbs, and any entity in which a Defendant or an Excluded D&O has a controlling interest. .

174. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes there are hundreds or thousands of members of the Class. Y-mAbs's common stock was actively traded on the NASDAQ throughout the Class Period.

175. Plaintiff will fairly and adequately protect the interests of the members of the Class. Plaintiff has retained competent counsel experienced in class action litigation under the federal securities laws to further ensure such protection; he is a member of the Class; his claims

are typical of the claims of all Class members; and he does not have interests antagonistic to, or in conflict with, those of the Class.

176. There are numerous questions of law or fact that are common to the Class and that predominate over any questions affecting individual members of the Class, including:

- whether Defendants violated the federal securities laws as alleged herein;
- whether the Defendants made materially false and misleading statements, or failed to disclose material information necessary to make the statements made not misleading, concerning FDA approval process for omburtamab;
- whether Defendants acted knowingly or recklessly in issuing false and misleading statements;
- whether the prices of Y-mAbs common stock during the Class Period was artificially inflated because of the Defendants' conduct complained of herein; and
- whether members of the Class were damaged by virtue of their investments in Y-mAbs common stock during the Class Period, and if so, the appropriate measure of damages.

177. A class action is superior to other available methods for the fair and efficient adjudication of this controversy since a multiplicity of actions could result in an unwarranted burden on the Court system and could create the possibility of inconsistent judgments. Moreover, a class action will allow redress for many persons whose claims would otherwise be too small to litigate individually. There will be no difficulty in the management of this action as a class action.

I. FRAUD-ON-THE-MARKET PRESUMTION OF RELIANCE

178. The market for Y-mAbs common stock was an efficient market during the Class Period for the following reasons, among others:

- Y-mAbs's stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient market;
- As a regulated issuer, Y-mAbs field periodic reports with the SEC and/or NASDAQ;

- Y-mAbs regularly communicated with investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major news wire services and through wide-ranging public disclosures such as communications with the financial press and other similar reporting services;

- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

- the Company was covered by multiple analysts;

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and

- Plaintiff and members of the Class purchased, acquired and/or sold Y-mAbs common stock between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts; and

- Unexpected material news concerning Y-mAbs was rapidly reflected in Y-mAbs share price.

179. Based upon the foregoing, the market for Y-mAbs promptly digested current information regarding Y-mAbs from all publicly available resources and reflected such information in Y-mAbs's share price. Accordingly, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

180. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;

- Y-mAbs common stock is traded in an efficient market;

- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

- the Company traded on the NASDAQ and was covered by multiple analysts;

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and

- Plaintiff and members of the Class purchased, acquired and/or sold Y-mAbs common stock between the time the defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

181. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

II. APPLICABILITY OF PRESUMPTION OF RELIANCE: *AFFILIATED UTE*

182. Neither Plaintiff nor the Class need prove reliance—either individually or as a class—because under the circumstances of this case, which involve omissions of material fact as described above, positive proof of reliance is not a prerequisite to recovery, pursuant to the ruling of the United States Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security. Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

Against Defendants for Violation of Sections 10(b) of The Exchange Act and Rule 10b-5 Thereunder

183. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

184. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

185. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the

other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Y-mAbs common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Y-mAbs common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

186. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Y-mAbs common stock. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Y-mAbs' business.

187. By virtue of their positions at the Company, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to defendants. Said acts and omissions of defendants were committed willfully or with reckless disregard for the truth. In

addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

188. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Y-mAbs, the Individual Defendants had knowledge of the details of Y-mAbs's internal affairs.

189. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Y-mAbs. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Y-mAbs's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Y-mAbs common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Y-mAbs' business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Y-mAbs common stock at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

190. During the Class Period, Y-mAbs common stock was traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Y-mAbs common stock at prices artificially inflated by defendants' wrongful conduct.

Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Y-mAbs common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Y-mAbs common stock declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

191. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

192. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's common stock during the Class Period, upon the disclosure that the Company had been disseminating false and misleading statements to the investing public.

COUNT II

Against Defendants Gad and Moller for Violation of Section 20(a) of the Exchange Act

193. Plaintiff incorporates each of the foregoing paragraphs as if fully set forth herein.

194. Defendants Gad and Moller were able to and did control, directly or indirectly, the content of the aforesaid public statements disseminated by Y-mAbs. With knowledge of the falsity of the statements contained therein and in reckless disregard of the true status of FDA analysis of omburtamab, Defendants Gad and Moller caused the complained of misstatements and omissions of material fact as alleged herein, and knowingly or recklessly failed in their duty to update or correct misleading statements issued by them or on their behalf.

195. Gad had actual knowledge of the misrepresentations and omissions of material fact set forth herein, or acted with reckless disregard for the truth in that he failed to ascertain and disclose such facts, even though such facts were available to him.

196. By virtue of his position as Chief Executive Officer of Y-mAbs during a crucial portion of the Class Period, Moller had actual knowledge of the misrepresentations and omissions of material fact set forth herein, or acted with reckless disregard for the truth in that he failed to ascertain and disclose such facts, even though such facts were available to him.

197. In particular, Defendants Gad and Moller had direct involvement in the day-to-day operations of the company and therefore had the power to control or influence the particular statements giving rise to the securities violations as alleged herein, and exercised the same.

198. As set forth above in Count I, Y-mAbs violated Section 10(b) and Rule 10b-5 promulgated thereunder by its acts and omissions as alleged in this Complaint.

199. As a result of the deceptive practices and false and misleading statements and omissions, the market price of Y-mAbs's common stock was artificially inflated during the Class Period. In ignorance of the false and misleading nature of the representations described above and the deceptive and manipulative devices employed by Defendants, Plaintiff and the other members of the Class, in reliance on either the integrity of the market and/or directly on the statements and reports of Defendants, purchased Y-mAbs's common stock at artificially inflated prices.

200. By virtue of their positions as Chairman (Gad) and Chief Executive Officers of Y-mAbs (Gad and Moller), Gad and Moller are liable for the company's violations of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, as alleged in Count I, pursuant to Section 20(a) of the Exchange Act.

201. Plaintiff and the other members of the Class have been damaged by the violations as described in this Count and seek recovery for the damages caused thereby.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and the other members of the Class, prays for judgment as follows:

16. Declaring this action to be a proper class action maintainable pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure and declaring Plaintiff to be a proper Class representative;

17. Awarding Plaintiff and the other members of the Class damages suffered as a result of the wrongs complained of herein, together with appropriate interest;

18. Awarding Plaintiff and the other members of the Class their costs and expenses of this litigation, including reasonable attorneys' fees and expert fees and other costs and disbursements; and

19. Awarding Plaintiff and the other members of the Class such other and further relief as may be just and proper under the circumstances.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

Dated: May 23, 2023

Respectfully submitted,

POMERANTZ LLP

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